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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,758	03/03/2006	Stephen Lewis Hart	ABL-012.1P US	1570

7590 02/23/2010

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
02/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,758	HART ET AL.	
	Examiner	Art Unit	
	CHRISTINA BRADLEY	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,12,13,32,35,42,51,54,65,76,80,84,97-101,105-107,110 and 111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,12,13,32,35,42,51,54,65,76,80,84,97-101,105-107,110 and 111.

DETAILED ACTION

Interview Summary

1. In a telephone conversation with David O'Brien on 1/29/2010, Applicants rejected the proposed Examiner's Amendment which would place the case in condition for allowance at this stage of prosecution (see Interview Summary mailed 1/28/2010 for details of the proposal).

Election/Restrictions

2. Applicant's election with traverse of SEQ ID NO: 8 in the reply filed on 09/24/2009 is acknowledged. The traversal is on the ground(s) that a lack of unity of invention has not been established to support the election of species requirement. Applicants' arguments have been considered and a new restriction requirement is made in addition to the election of species requirement previously issued.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 12, 13, 32, 110 and 111, drawn to a peptide comprising SEQ ID NO: 1.

Group II, claim(s) 35 and 42 drawn to a peptide comprising SEQ ID NO: 1 wherein the peptide is linked to a polycationic nucleic acid-binding component.

Group III, claims 51, 54, 65, 76, 80, 98, 105, drawn to non-viral transfection mixtures comprising a peptide comprising SEQ ID NO: 1.

Group III, claims 51, 54, 65, 76, 105 and 80 and 98, in part, drawn to non-viral transfection mixtures comprising a peptide comprising SEQ ID NO: 1 and a lipid component.

Group IV, claims 80 and 98, in part, drawn to non-viral transfection mixtures comprising a peptide comprising SEQ ID NO: 1 and not comprising a lipid component.

Group V, claim(s) 84, drawn to a viral vector encoding peptides comprising SEQ ID NO: 1.

Group VI, claim(s) 97 in part, drawn to a method of transfecting a cell *in vitro* using a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and a lipid component

Group VII, claim(s) 97 and 99 in part, drawn to a method of transfecting a cell *in vivo* and for treatment or prophylaxis of a condition caused by a defect and/or deficiency in a gene, comprising administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and a lipid component

Group VIII, claim(s) 97 and 100 in part, drawn to a method of transfecting a cell *in vivo* and for therapeutic or prophylactic immunisation, comprising administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and a lipid component.

Group IX, claim(s) 97 and 101 in part, drawn to a method of transfecting a cell *in vivo* and for anti-sense therapy, administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and a lipid component.

Group X, claim(s) 97 in part, drawn to a method of transfecting a cell *in vitro* using a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and not comprising a lipid component.

Group XI, claim(s) 97 and 99 in part, drawn to a method of transfecting a cell *in vivo* and for treatment or prophylaxis of a condition caused by a defect and/or deficiency in a gene, comprising administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and not comprising a lipid component.

Group XII, claim(s) 97 and 100 in part, drawn to a method of transfecting a cell *in vivo* and for therapeutic or prophylactic immunisation, comprising administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and not comprising a lipid component.

Group XIII, claim(s) 97 and 101 in part, drawn to a method of transfecting a cell *in vivo* and for anti-sense therapy, administering a non-viral transfection complex comprising a peptide comprising SEQ ID NO: 1 and not comprising a lipid component.

Group XIV, claim(s) 106, drawn to a bispecific antibody capable of binding to a virus and to a peptide comprising SEQ ID NO: 1.

Group XV, claim(s) 107, drawn to a fusion protein comprising a peptide comprising SEQ ID NO: 1 and an antibody capable of binding to a virus.

4. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: peptides comprising the amino acid sequence PX1X2X3T (SEQ ID NO: 1) wherein X1 is S, A or P, X2 is N or L and X3 is S, K, T or A, are know in the art. For example, Hallbrink et al. (US 2008/0234183) teach cell-penetrating peptides comprising PALKT instant SEQ ID NO: 6 (claim 26 and SEQ ID NOs: 3389-3392) and the use of cell-penetrating peptides in non-viral transfection mixtures (paragraphs 0141-0147 and Example 9). In addition, Galbraith et al. (WO 01/12816) teach the peptide TSLRPDITQPPSNSTT, which comprises instant SEQ ID NO: 8 (p. 17, peptide D), has a T at the N-terminus and is from 7 to 30 residues in length. In addition, Rose et al. (WO9704105) teach the peptide TDPALKT, which comprises instant SEQ ID NO: 6 (see p. 45, SEQ ID NO: 103), has a T at the N-terminus and is from 7 to 30 residues in length. In addition, Velicer et al. (US 5,976,787) teach a peptide comprising PPNTT SEQ ID NO: 9 at positions 82-86 (SEQ ID NO: 14). As a result, Groups I-XV lack unity of invention *a posteriori.*

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb